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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,528	07/07/2005	Thomas Julius Borody	3800027.00003 / 3704US	1484
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K&L Gates LLP 3580 Carmel Mountain Road Suite 200 San Diego, CA 92130				
EXAMINER				
HOBBS, LISA JOE				
ART UNIT		PAPER NUMBER		
1657				
MAIL DATE		DELIVERY MODE		
10/29/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,528

Applicant(s)

BORODY, THOMAS JULIUS

Examiner

Lisa J. Hobbs

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-17, 19-29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) 19-29 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/2009.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al.. ((2002) Clin. Microbiol. Rev. 15(3): 329-341) and Nakamura ((1953) Bacteriol. Rev. 17(3): 189-212), in view of Shimakita et al. (US 2003/0003527 A1) and Petri et al. (US 5272058 A).

A bi-phasic culture medium is claimed, along with a kit comprising the medium.

Clark et al. beneficially teach LE medium, a diphasic medium, which is a modification of Boeck and Drbohlav's medium. Clark et al. teach that Locke's solution is prepared by dissolving in 1 liter, sodium chloride, calcium chloride, potassium chloride, magnesium chloride, sodium phosphate, sodium bicarbonate, and potassium phosphate. Clark et al. further beneficially teach that egg slants are prepared as the solid phase of the LE medium (see, for example, page 332, column 2). Furthermore, Clark et al. teach that human or horse serum has been used in the Locke's solution liquid phase of LE medium of prior art versions of the medium (see, for example, page 334, column 2).

Clark et al. does not expressly teach a medium wherein the liquid phase contains peptone and optionally an antibiotic.

Nakamura beneficially teach that Boeck and Drbohlav's medium, Locke-egg-serum medium (LES medium) was the first successful cultivation of *E. histolytica* and since then, many modifications to their medium have been made. Nakamura beneficially teach that peptones as well as antibiotics, such as penicillin, have been used in the culture media of amoeba, as growth factors, and as means for eliminating bacteria from the cultures (see, for example, page 195 and 202). Furthermore, Nakamura beneficially teach that although an optimal salt concentration is 0.94%, *E. histolytica* can tolerate considerable changes in tonicity, and that phosphate buffer is essential (see, for example, page 200). Furthermore, Nakamura beneficially teach that according to Boeck and Drbohlav, amoebas grew best in cultures having an initial pH of 7.2 to 7.8 (see, for example, page 198).

Shimakita et al. and Petri et al. teach kits comprising media for bacterial growth. Petri et al. specifically teach kits for the detection of *E. histolytica*. Shimakita et al. teach "[t]he microorganism detecting kit has a feature that the specimen contact means contains a culture medium for culturing microorganisms. Thus, in the microorganism detecting kit according to the present invention, it is possible to prevent a reduction in activity of microorganisms deposited on the specimen contact means after contact of the compound(s) with the specimen" [0088].

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the medium disclosed by Clark et al., with respect to adding peptones and antibiotics, based upon the beneficial teachings provided by Nakamura with respect to the art-recognized benefits of adding peptones and antibiotics to culture mediums, as

discussed above. Clark et al. beneficially teach a bi-phasic medium which provides an egg slant and a liquid phase which has phosphate-buffered saline and serum. Furthermore, Nakamura beneficially teach that the LES medium described by Clark et al. has had many modifications, among which have been the addition of peptones as growth factors and antibiotics as means to eliminate unwanted bacteria from the culture. The result-effective adjustment of particular conventional working conditions (e.g., providing particular concentrations of ingredients within the medium, providing particular ingredients, such as particular antibiotics or peptones) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, as discussed by Nakamura above. Shimakita et al. and Petri et al. teach that kits for the detection of bacteria in any configuration desired by the user are well within the knowledge of one of skill in this art.

Response to Arguments

Applicant's arguments filed 15 July 2009 have been fully considered but they are not persuasive. Applicants argue that none of the cited references teaches the culture medium as claimed wherein there is no live E.coli in the liquid phase. The response states that the prior art of record does not teach simplifying a bi-phasic medium by reducing the number of ingredients and removing live E. coli bacteria. However, the claims are not drawn to a method of creating a medium, wherein the purpose of creating the medium and the purpose of the addition of certain ingredients would form limitations in the claim, the claims are drawn to a composition comprising a solid phase containing an egg or agar slope and a liquid phase consisting essentially of the list of ingredients, each of which is taught by the prior art as cited. Clark et al. teach the

basic composition, an egg slant and a liquid phase comprising salts, while Nakamura teaches peptones, phosphates, and antibiotics, to remove unwanted bacteria such as undesired E.coli. As well, Clark et al. teach the creation of axenic medium, "in which the parasite is grown in the absence of any other metabolizing cells" (p. 330).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh